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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/632,992 | 08/01/2003 | Jeffrey R. Horacek | ST8631US | 8982 |

22203 7590 11/23/2005

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| EXAMINER |
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MCKANE, ELIZABETH L

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| ART UNIT | PAPER NUMBER |
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1744

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/632,992

Applicant(s)

HORACEK ET AL.

Examiner

Leigh McKane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 102703.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

Claim Rejections – 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 2, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

An apparatus cannot be defined by itself. In claim 1, the “container” is comprised of “a rigid container.” Thus, the apparatus is defining itself.

In claims 2 and 13, “said container” renders the claim vague and indefinite because there are two “containers” recited in claim 1.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 6, 10, 11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Fricker et al. (US 6,325,968).

Fricker et al. teaches a cylindrical container for holding powdered reagents that interact with water to form an anti-microbial fluid. The container includes a rigid container 16 having a fluid inlet connectable to a source of water ("Water Fill") and a fluid outlet in fluid communication with items to be microbially deactivated. See Figure 3. A continuous fluid

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passage is defined through the container 16. A plurality of spaced-apart barrier elements 70,58 (Figure 4) are disposed within the fluid passage when cartridge C is located in the container 16. The elements together define two isolated compartments within the container 16 and are impervious to powdered reagents but permeable to chemical reagents dissolved in a liquid. See col.6, lines 1-4 and 14-18. The compartments each contain a reagent, such as acetylsalicylic acid, which reacts with water to form an antimicrobial (col.6, line 65 to col.7, line 2).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 2, and 6-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fricker et al. in view of Livingston et al. (US 5,759,501).

With respect to claims 1, 6-11, 13, and 14, Fricker et al. teaches a cylindrical container for holding powdered reagents that interact with water to form an anti-microbial fluid. The container includes a rigid container C having a fluid inlet (top of container) for water and a fluid outlet (bottom of container) in fluid communication with items to be microbially deactivated. See Figure 3. A continuous fluid passage is defined through the container C. A plurality of spaced-apart polymeric barrier elements 70,58 (Figure 4) are disposed within the fluid passage. They may be formed from porous polymeric materials such as polyethylene (col.6, lines 14-22).

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The elements together define two isolated compartments within the container **C** and are impervious to powdered reagents but permeable to chemical reagents dissolved in a liquid. See col.6, lines 1-4 and 14-18. The barrier elements are size specific (col.10, lines 50-64). The compartments each contain a reagent, such as acetylsalicylic acid, which reacts with water to form an antimicrobial (col.6, line 65 to col.7, line 2). The container is placed within an apparatus **12** for microbially deactivating instruments wherein the apparatus includes a circulation system, a chamber **14** for holding instruments, and a cavity **16** for receiving the container **C**. See Figure 2. Fricker et al. does not disclose connecting the fluid inlet to a source of water.

Livingston et al. discloses that it was known in the art at the time of the invention to connect the fluid inlet **27** of a reagent dispenser **11** to a source of water **55**. See Figure 1. As a connection between the fluid inlet and the water source prevents water from exiting that hasn't been contact with the reagent, it would have been obvious to connect the inlet of Fricker et al. with the water source.

As to claim 2, Fricker et al. teaches that the container **C** is formed of a polymeric material. See col.5, lines 57-57. Although it is not disclosed if container **C** is molded, it is taught to form portion **70** by molding (col.6, lines 5-9). It is deemed obvious to form the container **C** using a conventional method, such as molding.

With respect to claim 12, teaches using a microbial filter **190** to filter particles of 2μ and above or alternatively, that one of the compartments of the container **C** can function as the microbial filter. See col.10, lines 30-32.

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7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fricker et al. in view of Livingston et al., as applied to claim 1 above, and further in view of Siegel et al. (US 5,662,886).

The above combination fails to teach a removable moisture barrier covering the inlet and outlet. However, Siegel et al. discloses a similar apparatus wherein the inlet is covered with a removable moisture barrier (col.5, lines 15-17) to prevent powdered reagent loss. As both of the inlet and outlet of Fricker et al. would be susceptible to moisture entry and powder loss and as the presence of moisture in the container would have affected the reagents therein, it would have been obvious to provide the impermeable seal of Siegel et al. over both of the inlet and outlet of the container C of Fricker et al..

8. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fricker et al. in view of Livingston et al. and Siegel et al., as applied to claim 3 above, and further in view of Davis (US 6,158,580).

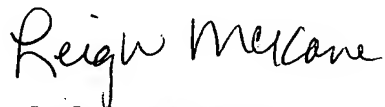
The combination does not teach a removable desiccant material within the container. Davis discloses a container for detergent wherein a removable desiccant material **140** is included within the container to remove moisture that would affect the detergent material within the container. See col.1, lines 19-29 and 46-64. As Fricker et al. teaches that the powdered reagent is reactive with water, it would have been obvious to include the desiccant material of Davis in the container in order to prevent water reaction before use. Moreover, it is deemed obvious to position the desiccant material anywhere in the container where it would have been easily removable, such as the fluid outlet.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Thursday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Leigh McKane
Primary Examiner
Art Unit 1744**